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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,691	08/29/2000	Gregg B. Fields	110.00680101	3203

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/03/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,691

Applicant(s)

FIELDS ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2002 and 03 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8 and 14-32 is/are pending in the application.
- 4a) Of the above claim(s) 22-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8, 14-21 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 4-8 and 14-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed on May 2, 2002 in Paper No. 13 is acknowledged and has been entered. Claims 1-3 and 9-13 have been canceled. Claims 4-8 and 14-18 have been amended. Claims 22-32 have been added.
2. The amendment filed on June 3, 2002 in Paper No. 15 is acknowledged and has been entered. Claims 4, 14, 22, 24, 27, and 32 have been amended.
3. Claims 4-8 and 14-32 are pending in the application. Claims 22-31 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.
4. Claims 4-8, 14-21, and 32 are currently under prosecution.

Election/Restrictions

5. Newly submitted claims 22-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The original claims were drawn to a polypeptide having an amino acid sequence that is a fragment of the continuous collagenous region of the major triple helical domain of the $\alpha 1$ chain of type IV collagen, and more particularly to a polypeptide comprising SEQ ID NO: 4, which is in the all D-form. Presently, claims 4-8, 14-21, and 32 are drawn to a polypeptide having the amino acid sequence set forth in SEQ ID NO: 1, which is in the all D-form. However, claims 22-31 are drawn to a polypeptide having the amino acid sequence set forth in SEQ ID NO: 3, which is in the all D-form. Accordingly, newly submitted claims 22-31 are drawn to a polypeptide that is biologically and chemically distinct from that which was originally claimed.

It is proper to restrict for examination purposes because the subject matter of the original claims (presently, claims 4-8, 14-21, and 32) and that of new submitted claims 22-31 are distinct, each from the other. Additionally, restriction for examination

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purposes is proper because the search that would be required to examine claims 22-31 has not been performed and therefore searching the additional subject matter would constitute a serious burden.

Since Applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for further prosecution on the merits. Claims 22-31 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR § 1.142(b) and MPEP § 821.03.

Claim Rejections

6. Unless specifically reiterated below, the grounds of claim rejections set forth in the previous Office action mailed January 2, 2002 (Paper No. 10) have been withdrawn.

35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6-8 and 16-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 1 and optionally conjugated to either a polyethylene glycol molecule or to a C₁₀ alkyl molecule to partially inhibit binding of human melanoma cells to type IV collagen *in vitro*, to partially inhibit invasion of MATRIGEL by human melanoma cells *in vitro*, and to partially inhibit formation human melanoma foci in an experimental mouse model of metastasis, wherein the melanoma cells are pre-incubated with the polypeptide before injection into the mouse, does not reasonably provide enablement for the use of any polypeptide of claim 1 to inhibit the binding, invasion, or metastasis of any tumor cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention commensurate in scope with these claims for the reasons set forth in the previous Office action mailed January 2, 2002 (Paper No. 10).

Applicants have traversed these grounds of rejection "in view of the presently pending claims" (Paper No. 13, page 6, paragraph 1). Applicants' arguments have been carefully considered but have not been found persuasive. Therefore, the grounds of rejection of claims 6-8 and 16-21 under 35 USC § 112, first paragraph set forth in the previous Office action mailed January 2, 2002 (Paper No. 10) are maintained.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office action mailed January 2, 2002 (Paper No. 10).

Applicants have traversed these grounds of rejection "in view of the presently pending claims" (Paper No. 13, page 6, paragraph 3). Applicants' arguments have been carefully considered but have not been found persuasive. Therefore, the grounds of rejection of claims 6-8 and 16-21 under 35 USC § 112, second paragraph set forth in the previous Office action mailed January 2, 2002 (Paper No. 10) are maintained.

35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the

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invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Knutson, et al (*Proceedings of the American Association for Cancer Research* **36**: 68, Abstract No. 407, 1995) for the reasons set forth in the previous Office action mailed January 2, 2002 (Paper No. 10).

Applicants have traversed these grounds of rejection arguing that there is no disclosure of the claimed polypeptide. In reply to Applicants' arguments, Knutson, et al disclose the D-enantiomer of IV-H1, a peptide comprising the amino acid sequence set forth in SEQ ID NO: 1. Although Knutson, et al do not disclose that the peptide inhibits binding of tumor cells to type IV collagen, inhibits tumor cell invasion into basement membranes, or inhibits tumor metastasis, these properties of the peptide are inherent. Therefore, the prior art polypeptide is deemed the same as the polypeptide of the instant claims, absent a showing of any differences. The Office does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics as the claimed polypeptide. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed polypeptide is different than that taught by the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Board of Patent Appeals and Interferences).

13. Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,013,628-A.

US Patent No. 6,013,628-A ('628) teaches a polypeptide having the amino acid sequence set forth in SEQ ID NO: 1. '628 teaches the polypeptide can be conjugated to a non-peptide moiety, namely a polyalkylene glycol. See columns 15 and 16, Table I; and columns 13 and 14, "Polypeptide Carrier Conjugates".

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35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 4-8, 14, 15, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,013,628-A in view of Dooley, et al (*Science* 266: 2019-2022, 1994).

US Patent No. 6,013,628-A ('628) teaches a polypeptide having the amino acid sequence set forth in SEQ ID NO: 1. '628 teaches the polypeptide can be conjugated to a non-peptide moiety, namely a polyalkylene glycol. '628 teaches that the polypeptide can be radiolabeled, or conjugated to a radioisotope, which is a cytotoxic agent. '628 teaches that the polypeptide can be administered to treat a patient diagnosed with a disease. However, '628 does not explicitly teach that the polypeptide can be in an all D-form.

Nevertheless, Dooley, et al teach that polypeptides comprised of D-form amino acids are not degraded by proteases and can be expected to remain intact after its administration to a patient. Furthermore, Dooley, et al disclose that the long duration of action of the all D-form polypeptide makes it of interest for *in vivo* studies.

In view of the teachings of Dooley, et al, therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have synthesized the polypeptide of '628 in the all D-form, because Dooley, et al teach that polypeptides in the all D-form are not degraded by proteases after administration to a patient. One of ordinary skill in the art at the time the invention was made would have been motivated to synthesize the all D-form of the polypeptide of '628 to study the activity of the all D-form *in vivo*.

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16. Claims 4-8, 14, 15, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,082,926-A in view of Dooley, et al (*Science* 266: 2019-2022, 1994) and US Patent No. 6,274,704-B1.

US Patent No. 5,082,926-A ('926) teaches a polypeptide having the amino acid sequence set forth in SEQ ID NO: 1. '926 teaches that the polypeptide can be radiolabeled, or conjugated to a radioisotope, which is a cytotoxic agent. '926 does not teach the polypeptide must comprise all L-form amino acids; nor does '926 teach the polypeptide can comprise all D-form amino acids. Additionally, '926 does not teach that the polypeptide can be conjugated to a non-peptide moiety such as a polyalkylene glycol.

Nevertheless, Dooley, et al teach that polypeptides comprised of D-form amino acids are not degraded by proteases and can be expected to remain intact after its administration to a patient. In addition, Dooley, et al disclose that the long duration of action of the all D-form polypeptide makes it of interest for *in vivo* studies.

Furthermore, US Patent No. 6,274,704-B1 teaches that polypeptides can be conjugated to polyethylene glycol (PEG) to render the polypeptide hydrophilic and can be used to treat a patient.

In view of the teachings of Dooley, et al, therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have synthesized the polypeptide of '926 in the all D-form and conjugate the polypeptide to PEG, because Dooley, et al teach that polypeptides in the all D-form are not degraded by proteases after administration to a patient and because '704 teaches that adding PEG to a polypeptide renders the conjugate hydrophilic. One of ordinary skill in the art at the time the invention was made would have been motivated to synthesize the all D-form of the polypeptide of '926 to study the activity of the all D-form *in vivo*. One of ordinary skill in the art at the time the invention was made would have been motivated to synthesize a conjugate of the polypeptide and PEG so that the polypeptide could be more easily administered in aqueous solution due to its hydrophilic nature.

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Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 4-8, 14, 15, and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,082,926-A in view of Dooley, et al (*Science* **266**: 2019-2022, 1994) and US Patent No. 6,274,704-B1 for the reasons set forth in the 35 USC §103(a) rejection above.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
November 20, 2002


ANTHONY C. CAPUTA
SUPERVISOR, PATENT EXAMINER
TECHNICAL STAFF